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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	066742-0026	6324
41552 7590 10/24/2008 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122				
EXAMINER				
KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
10/24/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/648,816

**Applicant(s)**

YEAMAN ET AL.

**Examiner**

CHIH-MIN KAM

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-69, 76, 79, 84 and 86 is/are rejected.
- 7) ☒ Claim(s) 70-75, 77, 78, 80-83 and 85 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-883)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Page No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed on September 2, 2008 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

#### ***Status of the Claims***

2. Claims 67-86 are pending.

Applicants' amendment filed on September 2, 2008 is acknowledged. Applicants' response has been fully considered. Claim 67 has been amended, and new claims 80-86 have been added. Therefore, claims 67-86 are examined.

#### **Withdrawn Claim Rejections - 35 USC § 102**

3. The previous rejection of claims 67-68 under 35 U.S.C. 102(b) as being anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April 1995), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 6 in the amendment filed September 2, 2008.

#### ***Maintained Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which discloses an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising the amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13.

Response to Arguments

Applicants request that the rejection be held in abeyance until there is an indication of allowable subject matter at which time Applicants will file a Terminal Disclaimer if appropriate. (page 6 of the response).

Applicants' response has been considered. Since a terminal disclaimer is not filed, the rejection is maintained.

5. Claims 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 7,067,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because

claims 67-69 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3. This is obvious variation in view of claims 1-8 of the patent which disclose a context-activating peptide comprising the amino acid sequence of SEQ ID NO:1, 2, 3 or 4, which contains the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys, and the specification indicates SEQ ID NO:1, 2, 3, or 4 has less anti-microbial activity than the anti-microbial peptide, RP-1 (column 4, line 50-column 5, line 56). Both sets of claims cite an antimicrobial peptide comprising the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys. Thus, claims 67-69 in present application and claims 1-8 in the patent are obvious variations of an antimicrobial peptide comprising the amino acid core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 86 is indefinite because the claim is an improper dependent claim and depends from claim 67 and 80-85 at the same time.

***New Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 67-68 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darveau *et al.* (U. S. Patent 5,409,898, April 1995).

Darveau *et al.* disclose cationic oligopeptides include Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly and the like, wherein the helix formed can be either left or right handed and can contain non-protein amino acids such as alpha, alpha-dialkyl amino acids (column 7, lines 46-48; column 10, lines 53-58), which has  $\alpha$  helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54; column 10, lines 59-64). Although Darveau *et al.* do not provide a specific example for the peptide containing alpha, alpha-dialkylamino acids, the reference does suggest the cationic oligopeptides can contain an alpha, alpha-dialkyl amino acid and form amphiphilic helices (column 10, lines 59-64). Thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that the cationic oligopeptides would contain alpha, alpha-dialkyl amino acids in the position of hydrophobic residues such as Leu, which results in the claimed invention (claims 67-68 and 84).

***Claim Objections***

9. Claims 70-75, 77, 78, 80-83 and 85 are objected to because the claims are dependent from a rejected claim.

***Conclusion***

10. Claims 67-69, 76, 79, 84 and 86 are rejected; and claims 70-75, 77, 78, 80-83 and 85 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

October 22, 2008